REMARKS

This is in response to the Final Action mailed on November 3, 2003. Reconsideration of this application is respectfully requested.

Disposition of Claims

The Final Action incorrectly indicated that Claim 19 is pending in this application. Claim 19 was canceled and its contents included in independent Claim 13 in the Amendment filed on August 19, 2003.

Restriction Requirement

In response to the Restriction Requirement, Applicants have canceled Claims 20-62 without disclaimer or prejudice to presenting them in later-filed continuing applications.

Claim Rejection

The Final Action rejected Claims 13-19 [sic, 18] under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Patent No. 5,450,847 to Kampfe et al. ("the Kampfe patent"). This rejection is respectfully traversed.

The invention of Claim 13 is directed to an injection apparatus comprising, *inter alia*, a fluid path comprising a mixing device, a reusable portion for delivering fluid to multiple patients and a per-patient disposable portion removably connected to the reusable portion.

The Kampfe patent, on the other hand, is directed to an apparatus and method for making various dose formulations of contrast media by mixing concentrated contrast medium and diluent for delivery to various containers. Specifically, the Kampfe patent discloses that "[e]nd 24 of pipe 22 can be connected with a variety of receiving containers (not shown), e.g., vials, bags or syringe arrangements." (Col. 8, lines 22-24.)

Further, the Kampfe patent discloses that the dose formulation device 10 includes a sterilization unit 48 including a steam generator 50 and a storage chamber 60 for sterilizing the feed pipes 16, 18, mixing chamber 20, delivery pipe 22 and sterile filter 46. Specifically, "[s]terilizing steam is conducted through the entire pipe arrangement 16, 18, 22, mixing chamber 20 and sterile filter 46 to storage chamber 60." (Col. 9, lines 48-50.)

Significantly, the Kampfe patent does not disclose or suggest that the pipe disposed between the sterile filter 46 and the discharge valve 66 (to which the dose containers are connected) is sterilized or otherwise maintained in a sterile condition. Applicants submit that this significant point is further validated by the following statement in the Kampfe patent: "Since a sterile filter 46 is provided downstream from metering element 30, all units, which are upstream from this sterile filter 46, remain in the sterilized condition." (Col. 9, lines 43-45.)

Even though the Kampfe patent discloses in a single sentence that the "mixing chamber can also alternatively be connected . . . directly to a patient for direct infusion (col. 6, lines 16-19), the Kampfe patent is silent as to the fluid path necessary for so doing. Further, the Kampfe patent does not address the need for maintaining the sterility of the pipe between the sterile filter 46 and the discharge valve 66 and any fluid line or path that necessarily would be present to connect the discharge valve 66 to the patient.

Consequently, Applicants submit that, at best, the Kampfe patent only discloses a reusable fluid path upstream of the sterile filter 46. The Kampfe patent's disclosure is silent as to the fluid path necessary to deliver fluid to the patient, the structure or features of the requisite fluid path, whether per-patient fluid paths would be necessary or used for each patient and, finally, how the sterility of the fluid path downstream of the sterile filter 46 would be maintained.

Further, Applicants submit that the Kampfe patent teaches away from the need or desirability of making the reusable system or any significant part thereof a disposable one, especially given the complex sterilization system included therein to provide reusability. The Kampfe patent contemplates a large and complex mixing apparatus containing containment vessels (of up to 100 liters), a steam generator 50, a storage vessel 60, a mixing chamber 20 and elaborate piping 16, 18, 22, including a feed pipe 52 for an outside water source.[1]

Based on the foregoing, Applicants submit that the Kampfe patent does not disclose or suggest each and every element or limitation of independent Claim 13 and the claims dependent thereon, and that the rejection based thereon should be withdrawn.

Claim Amendments Do Not Raise New Issues Or Add New Matter

Applicants submit that the above-provided claim amendments do not raise new issues that would require a new search, and thus may be properly entered and considered after final rejection. For example, the amendments to Claim 13 merely embellish the functionality of the reusable and disposable portions of the fluid path consistent with the

specification, namely that the reusable portion is used to deliver fluid to multiple patients and that the disposable portion is a per-patient disposable used to deliver fluid to a single patient.

New Claims 63-91 are fully supported by the specification (e.g., pgs. 4-6 and 11 and drawings (e.g., Figures 1 and 10). Specifically, the "Y element" limitation is supported by page 11, lines 15-24, of the specification and Figure 10 of the drawings. Therefore, no new mater has been added.

Conclusion

In view of the foregoing amendments and remarks, Applicants submit that the application is now in condition for allowance. Reconsideration of this application is respectfully requested.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being facsimile transmitted to the U.S. Patent and Trademark Office (Fax No. 703-872-9303) on January 26, 2004.

Dawn M. Dedola

[1] Applicants submit that even the terms used in the Kampfe patent -- e.g., vessels, chambers, pipes, feed pipes -- connote substantial size.